

**510 (k) Summary**

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**1. Submitter Information**

Company name	TaiDoc Technology Corporation
Contact person	Erica Li
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Date Prepared	May 29 <sup>th</sup> , 2007

**2. Name of Device**

Trade Names	Clever Chek TD-4209 Blood glucose monitoring system Clever Chek TD-4222 Blood glucose monitoring system Clever Chek TD-4225 Blood glucose monitoring system
Common Names/Descriptions	Blood Glucose Meter Blood Glucose Test Strips
Classification Names	Class II devices (21 CFR Section 862.1345, Glucose Test System)

**3. Predicate Device**

Trade/Proprietary Name:	ACCU-CHEK Aviva test strips
Common/Usual Name:	Blood Glucose test system
Manufacturer	Roche Diagnostics
510 (k) Number	K060620

#### 4. Device Description

Clever Chek TD-4209/ Clever Chek TD-4222/ Clever Chek TD-4225 blood glucose monitoring system consists of a meter and test strips. The system utilizes an electrochemical method-based meter and dry reagent biosensor (test strips) for blood glucose testing. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measurement of glucose in fresh whole blood and control solutions.

#### 5. Intended Use

Clever Chek TD-4209/ Clever Chek TD-4222/ Clever Chek TD-4225 blood glucose monitoring system is indicated for the quantitative measurement of glucose in fresh capillary whole blood taken from the finger and the alternative sites for self testing by persons with diabetes in the home or by healthcare professionals in healthcare facilities. Testing is done outside the body (in vitro diagnostic use).

The alternative site testing (the palm, the forearm, the upper arm, the calf and the thigh) in this system can be used only during steady-state blood glucose conditions.

Limited to professionals, this system can also test on neonate blood, where is from the heel.

#### 6. Comparison to Predicate Device

Clever Chek TD-4209/ Clever Chek TD-4222/ Clever Chek TD-4225 blood glucose monitoring system has equivalent technological characteristics as the ACCU-CHEK Aviva blood glucose test system (K060620). Clever Chek TD-4209/ Clever Chek TD-4222/ Clever Chek TD-4225 blood glucose monitoring system also has the similar intended use as the ACCU-CHEK Aviva blood glucose test system

#### 7. Performance Studies

The performance of Clever Chek TD-4209/ Clever Chek TD-4222/ Clever Chek TD-4225 blood glucose monitoring system was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that the performance of this system meets its intended use.

## 8. Conclusion

Clever Chek TD-4209/ Clever Chek TD-4222/ Clever Chek TD-4225 blood glucose monitoring system demonstrates satisfactory performance and is suitable for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

TaiDoc Technology Corporation  
c/o Ms. Erica Li  
Management Representative  
4F, 88, Sec. 1, Kwang Fu Road  
San Chung, Taipei County, Taiwan 241

OCT 26 2007

Re: k071493  
Trade Name: Clever Chek TD-4209 Blood Glucose Monitoring System, Clever Chek  
TD-4222 Blood Glucose Monitoring System, Clever Chek TD-4225 Blood Glucose  
Monitoring System  
Regulation Number: 21 CFR 862.1345  
Regulation Name: Glucose test system  
Regulatory Class: Class II  
Product Code: NBW, CGA  
Dated: October 15, 2007  
Received: October 18, 2007

Dear Ms. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

*Jean M. Cooper, M.S., D.V.M.*

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number:

K071493

Device Name: Clever Chek TD-4209 Blood glucose monitoring system  
Clever Chek TD-4222 Blood glucose monitoring system  
Clever Chek TD-4225 Blood glucose monitoring system

### Indications for Use:

The Clever Chek TD-4209/ Clever Chek TD-4222/ Clever Chek TD-4225 Blood glucose monitoring system is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus.

The alternative site testing in the Clever Chek TD-4209/ Clever Chek TD-4222/ Clever Chek TD-4225 Blood glucose monitoring system can be used only during steady-state blood glucose conditions.

Professionals may use the Clever Chek TD-4209/ Clever Chek TD-4222 Blood/ Clever Chek TD-4225 glucose monitoring system to test neonatal blood from the heel, but may not be used in screening for neonatal hypoglycemia.

Prescription Use X

AND/OR

Over-The-Counter Use X

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Carol Benson  
Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

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